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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,547	12/05/2003	Ronald W. Marsh	P-4154P1	8789

26253 7590 05/14/2007
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EXAMINER

GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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05/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/728,547	Applicant(s) MARSH ET AL.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's communication of 3/2/2007.
Currently amended claims 1-20 are pending and rejected below.

Response to Arguments

Applicant's arguments filed 3/2/2007 have been fully considered but they are not persuasive. Applicant has argued that the newly amended claim language and clarification that the clamp reduces but does not occlude is not disclosed in the prior art of record. As explained in the rejection below, it is examiner's position that Schaffer clamp is fully capable of reducing, but not fully occluding the inner diameter. It is examiners position that the prior art of record is fully capable of satisfying all structural, functional, operational, and spatial limitations as currently written into the claims. Therefore the rejections stand.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha et al. (U.S. Patent Number 5,480,389) in view of Schaffer (U.S. Patent Number 5,429,616). McWha discloses a spinal epidural needle set (figure 3) comprising an elongate tube (14) with a sharpened distal end (15), an attached hub (22,26,34,51,40) and a spinal needle (12) and indicia for location (34). The epidermal and spinal needle system is fully capable of performing all the associated functional language and claim limitations. Schaffer discloses a hub/needle/catheter (see figures 2 and 5) with a resilient member (50) permanently mounted within a hub (26), and a deformable U-shaped clamp with living hinge (24) with a releasable latch push tab (60) and support arms, that is oriented for perpendicular movement to the elongate tube. Further the resilient member defines a radiused portion and the readiused portion of the pair of legs (48) has a radius substantially the same as the radiused portion of the resilient member, and a second radiused portion (figures 3-6). The resilient member and clamp of Schaffer are fully capable of performing all the associated functional language and claim limitations.

Mc Wha discloses the claimed invention except for the resilient member and clamp. Schaffer teaches that it is known to use a resilient member and clamp as set forth in paragraphs beginning at columns 1-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the epidermal needle system as taught by Mc Wha with the resilient member and clamp as taught by Schaffer, since such a modification would provide the epidermal needle system with the resilient member and clamp for providing inward collapsing of the side wall portion and to reduce or occlude the apparatus.

Concerning the newly amended claim language that the clamp causes a "strain to at least a portion of the resilient member thereby reducing but not occluding...", It is examiners position that the resilient member and clamp of Schaffer would be fully capable and known (to a PHOSITA) that the clamp would reduce but not occlude the inner diameter of the opening. As evidenced in figures 3 through 6 of Schaffer, the clamp has a range of operation that causes the inner diameter to be from fully open to occluded, but also has an intermediary position of a "reduced" in diameter state (when not fully open or fully closed). Therefore it is examiners position that the clamp would be fully capable of reducing but not occluding.

In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the clamp reduce the inner diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955). In this case it would be obvious for a

person having ordinary skill in the art at the time of the invention, to modify the range of the clamp (how closed it becomes or how much it reduces the inner diameter) in order to limit the amount of fluid flow through an inner diameter or reduce the space to secure the clamp to another body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180.

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The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons